BIGPHARMA

FDA Blasted for Pursuing Deal With Data Provider That Has 'Ties to Opioid Makers + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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FDA Is Blasted by Advocates for Pursuing a Deal With Data Provider That Has Ties to Opioid Makers

STAT News reported:

Several advocacy groups are blasting a Food and Drug Administration proposal to work with a Denver Health surveillance system for monitoring misuse of prescription opioids over long-standing ties the operation has to the pharmaceutical industry.

At issue is the Research, Abuse, Diversion, and Addiction-Related Surveillance System, or RADARS, which was originally created as an in-house monitoring program by Purdue Pharma and later sold to the Denver Health and Hospital Authority. The RADARS system primarily collects real-world evidence from patients about opioid treatment programs, which is why the FDA is interested in its data.

But RADARS also works with the pharmaceutical industry in certain ways that advocacy groups argue are problematic. For instance, RADARS provides consulting services to drug companies as they prepare for meetings with FDA advisory panels, according to its website. These meetings are convened by the agency to determine whether a medicine should be recommended for a particular use.

CureVac Touts COVID Vax Data as Platform Validation, Despite Grade 3 Adverse Events

Fierce Biotech reported:

CureVac says its monovalent and bivalent COVID-19 vaccine candidates produced meaningful immune responses at lower doses than similar approved vaccines and were generally safe — though grade 3 adverse events were recorded in a few of the health volunteers.

The phase 2 study is evaluating a single booster dose of a monovalent vaccine candidate CV0601, which encodes the spike protein of the Omicron BA.4-5 variant, and three different dose levels of a bivalent candidate dubbed CV0701, which encodes the spike protein of the Omicron BA.4-5 variant and original SARS-CoV-2 virus. CureVac's shots were compared to an unnamed, approved bivalent mRNA-based COVID-19 vaccine in healthy volunteers.

All dosing levels of CureVac's GSK-partnered mRNA vaccines fall below those used in mRNA COVID-19 vaccines approved in the U.S. and EU, such as Moderna's Spikevax or Pfizer-BioNTech's Comirnaty.

Among 87 healthy participants receiving the CV0701 low dose, 1% had a grade 3 adverse event (AE) — which is considered severe or medically significant but not immediately life-threatening. Of 84 participants receiving the middle dose, 2% had a grade 3 AE, while no grade 3 or above AEs occurred in the highest CV0701 dosing group, according to a presentation accompanying the press release.

The company is also advancing an mRNA flu vaccine program in partnership with GSK as well. The Big Pharma first signed the mRNA deal with CureVac in July 2020 in the first months of the global COVID-19 pandemic.

Health Canada Approves RSV Vaccine for Maternal Immunization

CBC News reported:

Health Canada has approved a new vaccine geared toward protecting two groups most severely affected by the respiratory syncytial virus (RSV) newborns, who would receive antibodies through maternal immunization, and Canadians over 60.

Pfizer Canada's bivalent vaccine, called Abrysvo, aims to prevent lower respiratory tract disease caused by the virus.

It is the first RSV vaccine in Canada approved for use in pregnancy to provide protection for infants from birth to six months of age, and the second approved for seniors aged 60 and over.

The U.S. Food and Drug Administration approved the vaccine for those same two groups in 2023.

Merck Looks to Join the Obesity Drug Frenzy

Bloomberg reported:

Merck & Co. is seeking new obesity-fighting drugs called GLP-1s, joining a host of companies angling for a slice of the exploding market.

The drug giant is looking for therapies that provide health benefits for diabetes and other disorders alongside weight loss, Chief Executive Officer Rob Davis said Thursday at an investor conference hosted by Goldman Sachs Group Inc. Merck is seeking opportunities through its own drug development as well as deals, he said.

Pioneered by Eli Lilly & Co and Novo Nordisk A/S, weight-loss medications are causing a frenzy among drugmakers, with Amgen Inc. and Pfizer Inc. conducting studies. Merck has an experimental GLP-1 for non-alcoholic fatty liver disease, which the company will continue to invest in, Davis said, but it failed to recognize the potential in the drugs right away.

"We did not see the GLP-1s early to potentially have the activity they've had," Davis said. Showing benefits beyond weight loss may make it easier to get reimbursement for the drugs, he said. "If you can show cardiovascular outcome, if you can show a diabetes outcome, which you're starting to see data for, if you can see fatty liver disease benefits," he said, "that is an area where we see opportunity."

Wegovy Maker Novo Nordisk Enters Research Tie-Ups With U.S. Biotech Firms

Reuters reported:

Blockbuster weight-loss drug maker Novo Nordisk (NOVOb.CO) announced on Thursday research collaborations with two U.S. biotech firms, part of its efforts to stay ahead in big pharma's race to develop more treatments for cardiometabolic diseases.

Novo, a Danish drugmaker whose share price rose 49% last year due to soaring demand for its weight-loss medicine Wegovy, said the partnerships with Omega Therapeutics (OMGA.O) and Cellarity Inc. could lead to new treatments for people living with obesity and a type of liver disease known as MASH.

Can Denmark's World-Beating Drugs Maker Stay Ahead?

BBC News reported:

Late last year, Danish pharmaceutical company Novo Nordisk became Europe's most valuable company, for a short time at least.

Well-known in business circles, but hardly a household name, Novo Nordisk had not previously been seen as a big player in the drugs industry, let alone a titan of the European stock market.

But it leapt to the top of the league table and was valued at $428 billion (£342bn) because it had discovered the Holy Grail of all drugs. One that millions of people want and need across the Western World and beyond.

It is knocking at an open door — Goldman Sachs research predicts that the anti-obesity drugs market is worth some $6 billion this year. But by 2030, it could grow by more than 16 times to $100 billion.

Wegovy, Ozempic Not Linked to Increase in Suicidal Thoughts, U.S. Study Finds

Reuters reported:

A large U.S. study found no evidence that taking Novo Nordisk's (NOVOb.CO) Ozempic or Wegovy is tied to an increase in suicidal thoughts, researchers reported on Friday.

Both Ozempic for type 2 diabetes and the obesity treatment Wegovy have the same active ingredient, semaglutide.

Instead, the analysis of electronic medical record data from more than 1.8 million patients found a lower risk of new and recurrent suicidal thoughts in those taking semaglutide compared to those using other medications for weight loss or diabetes.

Concerns over reports of suicidal ideation associated with semaglutide led to an investigation by the European Medicines Agency, while the U.S. Food and Drug Administration has listed suicidal ideation as a potential safety signal for GLP-1 drugs.

U.S. Faces 'Tragic' Rise in Syphilis Cases With Life-Saving Drug in Short Supply

The Guardian reported:

Record-high rates of syphilis and an accompanying shortage of the preferred antibiotic to treat the disease will make it one of the most pressing public health concerns in 2024, an association of public health leaders said.

Syphilis is a sexually transmitted infection that was once rare but has made a "tragic" return in an era of reduced funding for public health. The 27-year high in cases has also strained manufacturing of the preferred antibiotic to treat syphilis, a penicillin formulation called Bicillin L-A.

Bicillin has been in "limited supply" since June 2023, according to Pfizer, the only manufacturer of the antibiotic in the U.S. A spokesperson for the company said the sheer volume of new cases strained the supply. In just one example of the regional extremes, cases of congenital syphilis in Houston, Texas, surged from 16 in 2016 to 151 in 2021.

U.S. FDA to Allow Florida to Import Cheaper Drugs From Canada

Reuters reported:

The U.S. Food and Drug Administration (FDA) on Friday authorized Florida to directly import prescription drugs from Canada, making it the first state to get approval for a plan aimed at bringing cheaper medicines to Americans.

Drug costs in the United States are higher than any other nation in the world by two to three times.

Supporters of the importation policy, which has been considered for years, have said buying drugs from another country could help lower costs in the United States.

The pharmaceutical industry has opposed the plans and said it will not lead to lower costs for consumers and put the safety of the U.S. drug supply at risk.

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